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269. (New) The infant simulator of claim 48<sup>2</sup> wherein (i) the infant simulator further includes at least two diapers, with each diaper equipped with a means effective for transmitting a different diaper-changed signal, and (ii) the diaper-changed signal receiving means alternates between the different diaper-changed signals as the signal capable of being received so as to end the diaper-change episode.

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270. (New) An infant simulator, comprising:

- (a) a doll;
- (b) a diaper-change system within the doll for periodically effecting a diaper-change episode, including at least:
  - (i) a means for generating a perceptible soiled-diaper signal; and
  - (ii) a means in communication with the soiled-diaper signal generating means for arresting the soiled-diaper signal in response to receipt of a diaper-changed signal; and
- (c) a diaper configured and arranged to be fitted over the lower torso of the doll as a diaper and having ~~an orientation-sensitive means effective for transmitting the diaper-changed signal to the soiled-diaper signal arresting means when oriented relative to the doll in accordance with the orientation achieved by fitting the diaper on the doll~~<sup>C2</sup>

Amended  
 115, C2  
 C  
 C  
 C

### REMARKS

No claims have been deleted. Claims 48, 50, 70, 208, 209 and 255 have been amended. New claims 268-270 have been added. Claims 1-270 remain pending in the application.

Applicant thanks the Examiner for indicating that claims 70, 228-235 and 261-267 are allowable over the prior art of record.

## *Support*

Support for the amendment at page 23, line 28 can be found from the context of the sentence itself.

Support for the amendment at page 69, line 1 can be found in Figure 2e.

Support for the amendments on page 72 can be found in Figure 2f.

Support for the amendments to claims 208 and 209 can be found on page 58, lines 28-30; page 59, lines 6-10; page 43, lines 1-10; page 48, lines 6-15; page 52, line 26 through page 53, line 5; page 72, line 18 through page 73, line 2; page 75, line 26 through page 76, line 10; and page 79, lines 13-27 of the specification.

Support for new claim 268 can be found in Figure 2e.

Support for new claim 269 can be found in Figure 2e.

Support for new claim 270 can be found on page 37, line 24 through page 38, line 15 of the specification.

***Election/Restriction***  
***Under 35 U.S.C. § 121***

***1.0*** The Examiner has indicated that the application contains claims directed to the patentably distinct species of an infant simulator with (i) a temperature sensor (claims 1-25), (ii) a compression sensor (claims 26-46), (iii) a diaper changing system (claims 47-70), (iv) a rocking-request system (claims 71-104), (v) a feeding and burping-request system (claims 105-162), (vi) a fussing system (claims 163-207), and (vii) a general demand episode system (claims 208-267).

Applicant affirms election of species (iii) (claims 47-70) directed to an infant simulator having a diaper-change system.

***1.1*** The Examiner has further indicated that the claims within species (iii) include claims directed to the patentably distinct subspecies of a user identification system having an identification signal receiving means of (a) a voice or fingerprint recognition system, and (b) a keyhole.

Applicant affirms election of subspecies (b) directed to a user identification system having a keyhole as the identification signal receiving means.

***Informalities***

***2.0*** The Examiner has indicated that the specification includes several typographical errors.

Applicant thanks the Examiner for noting the typographical errors contained in the specification. The specification has been amended to correct these errors, as well as several additional typographical errors identified by Applicant.

***Objections/Rejections***  
***Under 35 U.S.C. §§ 102 and 103***

**3.0**     *The Examiner has rejected claims 208 and 254 as anticipated by the NASCO Manual.*

**3.1**     INFANT SIMULATOR WITH  
CONTENTED SIGNAL FEATURE  
(CLAIM 208)

*SUMMARY OF CITED REFERENCE*

**The NASCO Manual** discloses a parenting manikin programmed to periodically initiate care periods during which the manikin will cry until an appropriate care key - selected from a set of five different care keys- is inserted into the manikin. The NASCO Manual further discloses that the manikin will coo or burp when the correct care key is inserted, and then coo again several minutes later to indicate the end of the care period and the need to reinsert the same care key to avoid further crying.

*SUMMARY OF CLAIMED INVENTION*

The embodiment of the Present Claimed Invention as set forth in Claim 208 (hereinafter "CONTENTED SIGNAL EMBODIMENT"), is directed to an infant care simulation system for use in an infant care training program, wherein the infant simulator includes (A) a demand system comprising (i) a means for generating a perceptible demand signal (*e.g.*, a crying sound), (ii) a means for inhibiting the demand signal in response to receipt of a satisfaction signal so long as the satisfaction signal is continuously received by the demand signal inhibiting means (*e.g.*, holding a key within a keyhole against a biasing means), and (iii) a demand duration timer in communication with the demand signal generating means for terminating generation of the demand signal at the end of a demand period, and (B) a feedback system including (i) a means for generating a perceptible contented signal (*e.g.*, a cooing sound), and (ii) a means for initiating generation of the contented signal at the end of the demand period provided the satisfaction signal is being received by the demand system at the end of the demand period (*e.g.*, the cooing sound is generated only when the key is detected within the keyhole when the timer signals the

end of the demand period). The contented signal thereby functions to indicate to a care provider that the demand period has ended, the demand signal has been terminated, and the satisfaction signal need no longer be continuously provided to the simulator (*e.g.*, the care provider can remove the key from the keyhole).

*THE NASCO MANUAL DOES NOT DISCLOSE  
THE CONTENTED SIGNAL EMBODIMENT*

An anticipation rejection under 35 U.S.C. §102 requires that the cited reference(s) disclose each and every element of the claimed invention. *See, Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986); *Kloster Speedsteel AB et al. v. Crucible Inc. et al.*, 230 U.S.P.Q. 81, 84 (Fed. Cir. 1986). Accordingly, the “exclusion of a claimed element from a prior art reference is enough to negate anticipation by that reference.” *Atlas Powder Co. v. E.L duPont De Nemours & Co.*, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984).

For purposes of simplifying a comparison of the parenting manikin described in the NASCO Manual and the Contented Signal Embodiment of the Present Claimed Invention, the Contented Signal Embodiment of the Present Claimed Invention can be described in the language of the NASCO Manual as a parenting manikin programmed to (i) periodically cry for a care period unless an appropriate care key is continuously inserted into the manikin throughout the duration of the care period, and (ii) signal the end of the care period (*i.e.*, the ability to withdraw the care key without reinitiating crying) by generating a contented signal when the care key is detected within the manikin at the end of the care period.

The NASCO Manual does NOT disclose the Contented Signal Embodiment of the Present Claimed Invention. The chronological and functional relationship between generation of the demand signal (*e.g.*, the crying sound), receipt of the satisfaction signal (*e.g.*, insertion of the key into the keyhole) and generation of the contented signal (*e.g.*, the cooing sound) in the parenting manikin described in the NASCO Manual is completely different than that in the Contented Signal Embodiment of the Present Claimed Invention. The parenting manikin described by the NASCO Manual requests insertion of a care key twice for each care period, with a coo/burp



generated after the first insertion to signal insertion of the correct care key, and a coo/burp generated at the end of a care period to signal the care-provider to reinsert the care key to prevent reinitiation of crying. In contrast, the Contented Signal Embodiment of the Present Claimed Invention is directed to an infant simulator requiring receipt of a satisfaction signal (*e.g.*, insertion of a care key) *continuously* throughout each demand period, with a contented signal generated at the end of the demand period - *provided the satisfaction signal is being received by the infant simulator at the end of the demand period* - for purposes of signaling the care-provider that the demand period has ended and the satisfaction signal need no longer be continuously provided to the simulator.

### 3.2 INFANT SIMULATOR WITH IDENTIFICATION SYSTEM FEATURE (CLAIM 254)

#### *SUMMARY OF CITED REFERENCE*

**The NASCO Manual** discloses a parenting manikin programmed to periodically cry until an appropriate care key - selected from a set of five different care keys- is inserted into the manikin. The NASCO Manual further discloses that the manikin will coo or burp when the correct care key is inserted, and then coo again several minutes later to indicate the end of the care period and the need to reinsert the same care key to avoid further crying.

#### *SUMMARY OF CLAIMED INVENTION*

The embodiment of **The Present Claimed Invention** as set forth in Claim 254 (hereinafter "FIRST IDENTIFICATION SYSTEM EMBODIMENT"), is directed to an infant care simulation system for use in an infant care training program, wherein the infant simulator includes (A) a demand system comprising (i) a means for generating a perceptible demand signal (*e.g.*, a crying sound), and (ii) a means for arresting the demand signal in response to receipt of a satisfaction signal (*e.g.*, insertion of a key into a keyhole), and (B) a care-provider identification system comprising (i) a means for receiving an identification signal (*e.g.*, keyhole effective for

receiving an identification key attached to the wrist of an assigned care provider by a tamper indicating wristband), and (ii) a means effective for preventing arresting of the demand signal, even though the satisfaction signal has been received by the satisfaction signal arresting means, until the identification signal is received by the identification-signal receiving means.

*THE NASCO MANUAL DOES NOT DISCLOSE  
THE IDENTIFICATION SYSTEM FEATURE*

An anticipation rejection under 35 U.S.C. §102 requires that the cited reference(s) disclose each and every element of the claimed invention. *See, Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986); *Kloster Speedsteel AB et al. v. Crucible Inc. et al.*, 230 U.S.P.Q. 81, 84 (Fed. Cir. 1986). Accordingly, the “exclusion of a claimed element from a prior art reference is enough to negate anticipation by that reference.” *Atlas Powder Co. v. E.L duPont De Nemours & Co.*, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984).

For purposes of simplifying a comparison of the parenting manikin described in the NASCO Manual and the First Identification System Embodiment of the Present Claimed Invention, the First Identification System Embodiment can be described in the language of the NASCO Manual as a parenting manikin programmed to periodically cry until an appropriate care key is inserted into the manikin *and* the assigned care-provider signals the parenting manikin that they are present, such as by insertion of an identification key attached to the wrist of the assigned care provider by a tamper indicating wristband.

The NASCO Manual simply does NOT disclose any form of a care provider identification system. The parenting manikin described by the NASCO Manual requires only the insertion of a single care key at the beginning and end of a care period to terminate crying.

*THE NASCO MANUAL TEACHES AWAY FROM  
AN IDENTIFICATION SYSTEM FEATURE*

A prior art reference must be considered in its entirety (*i.e.*, as a whole) including portions that would lead away from the claimed invention. *See, W.L. Gore & Associates, Inc. v. Garlock,*

Inc., 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), and M.P.E.P. § 2141.02 [PRIOR ART MUST BE CONSIDERED IN ITS ENTIRETY, INCLUDING DISCLOSURES THAT TEACH AWAY FROM THE CLAIMS].

The NASCO Manual expressly states that the assigned care provider can arrange for someone to baby-sit the manikin (*i.e.*, arrange for someone else to insert the appropriate care key at the appropriate time and record such action on a “response sheet”). The NASCO Manual specifically recites at page 6 of the manual that “*Baby-sitting is a very realistic option within this simulation*”. In contrast, a primary function of the identification system feature of the Present Claimed Invention is to prevent this very type of activity for purposes of ensuring that the assigned care provider is at least present while the demands of the infant simulator are being satisfied.

**4.0**     *The Examiner has rejected claim 47 as obvious over the NASCO Manual in view of Corris et al.*

*SUMMARY OF CITED REFERENCES*

**The NASCO Manual** discloses a parenting manikin programmed to periodically cry until an appropriate care key - selected from a set of five different care keys- is inserted into the manikin.

**Corris et al.** (United States Patent No. 4,231,184) discloses a remote control doll capable of being remotely activated to cry and raise its arms. The crying sound can be interrupted by inserting a pacifier or bottle into the mouth of the doll.

*SUMMARY OF CLAIMED INVENTION*

The embodiment of **The Present Claimed Invention** as set forth in Claim 47 (hereinafter “FIRST DIAPER-CHANGE EMBODIMENT”), is directed to an infant care simulation system for use in an infant care training program, wherein the infant simulator includes (A) a diaper-change system including at least (i) a means for generating a perceptible soiled-diaper signal (*e.g.*, a crying



sound), and (ii) a means for arresting the soiled-diaper signal in response to receipt of a diaper-changed signal (e.g., a magnetic actuated switch), and (B) a diaper having a means effective for transmitting the diaper-changed signal to the soiled-diaper signal arresting means when fitted on the doll (e.g., a diaper having a magnet attached so as to be properly positioned and oriented to shut off the magnetic actuated switch when the diaper is fitted onto the doll).

*LEGAL REQUIREMENTS FOR ESTABLISHING  
PRIMA FACIE CASE OF OBVIOUSNESS*

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, NOT in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). *See*, M.P.E.P. § 2143.

*CITED REFERENCES LACK MOTIVATION  
TO MODIFY THE PRIOR ART DEVICES  
TO ACHIEVE THE PRESENT CLAIMED INVENTION*

In order to determine the propriety of an obviousness rejection, it is necessary to ascertain whether or not the reference motivates one of ordinary skill in the relevant art, having the reference before him, to make the proposed substitution, combination, or other modification. In re Linter, 458 F.2d 1013, 173 USPQ 560, 562 (CCPA 1972). Obviousness can only be established where there is some teaching, suggestion or motivation in the prior art or in the knowledge generally available to one of ordinary skill in the art, to combine the references and produce the claimed invention. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *See*, M.P.E.P. §2143.01.

Neither the NASCO Manual nor Corris et al. teach or suggest an infant simulator wherein the means for transmitting a satisfaction signal (e.g., a magnet) is retained within an actual diaper, with the satisfaction signal transmitted to the satisfaction signal receiving means (e.g., a magnetic actuated switch) when the diaper is fitted onto the simulator. The NASCO Manual describes the use of care keys inserted into a slot in the manikin. Corris et al. describes the use of a pacifier or bottle inserted into the mouth of the doll. Neither of these methods requires a care provider to carry a diaper and actually diaper the manikin/doll in order to end a crying sound.

The Examiner, in recognition of the lack of any express motivation in the cited references to modify the manikin disclosed in the NASCO Manual or the doll disclosed in Corris et al. to achieve the First Diaper-Change Embodiment of the Present Claimed Invention, argues that *"Although Corris et al. does not teach specifically a diaper with means for transmitting a diaper-changed signal to a soiled diaper [signal] arresting means, it would have been obvious ... to apply the transmission means of Corris et al. in the form of any infant demand/satisfaction system onto the doll of Nasco International Inc. to have a diaper which when changed will arrest the complaint generating means."* Applicant respectfully submits that while the reasoning of this statement initially appears sound, the conclusion offered by the Examiner (i.e., those skilled in the art are motivated to require diapering of the manikin/doll in order to end crying) is not a conclusion which can be drawn from the statement. The proper conclusion to be drawn from the Examiner's statement is that those skilled in the art possess the technology necessary to construct a manikin/doll requiring diapering of the manikin/doll in order to end crying should they ever be motivated to do so. However, neither the NASCO Manual nor Corris et al. provide such motivation. Such motivation is provided only after reading Applicant's disclosure and using such disclosure as a blueprint to modify the teaching of the prior art. See, In Re O'Farrell, 7 U.S.P.Q.2d 1673, 1681 (Fed. Cir. 1988) (rejection of the subsequent invention as obvious based upon the unguided selection of components from various references is improper. There must be some indication from the *prior art* as to which of the possible choices is likely to be successful.).

**5.0** *The Examiner has rejected claims 48-50, 52-55, 58-60, 62-69, 209-212, 215-217, 219-227, 255-256 and 259-260 as obvious over the NASCO Manual in view of Corris et al. and further in view of Schertz et al.*

**5.1** INFANT SIMULATOR WITH  
CONTENTED SIGNAL FEATURE  
(CLAIMS 209-212, 215, 217, and 219-227)

*SUMMARY OF CITED REFERENCES*

**The NASCO Manual** discloses a parenting manikin programmed to periodically initiate care periods during which the manikin will cry until an appropriate care key - selected from a set of five different care keys- is inserted into the manikin. The NASCO Manual further discloses that the manikin will coo or burp when the correct care key is inserted, and then coo again several minutes later to indicate the end of the care period and the need to reinsert the same care key to avoid further crying.

**Corris et al.** (United States Patent No. 4,231,184) discloses a remote control doll capable of being remotely activated to cry and raise its arms. The crying sound can be interrupted by inserting a pacifier or bottle into the mouth of the doll.

**Schertz et al** (United States Patent No. 5,509,810) discloses an interactive neonatal resuscitation training simulator including a robotic infant capable of simulating the actions of a newborn requiring resuscitation (*e.g.*, low heart rate) and responding to the efforts of an attending physician to resuscitate the infant (*e.g.*, change color in response to receipt of appropriate medical care).

*SUMMARY OF CLAIMED INVENTION*

The embodiment of **The Present Claimed Invention** as set forth in Claims 209-212, 215, 217, and 219-227 (hereinafter "CONTENTED SIGNAL EMBODIMENT"), is directed to an infant care simulation system for use in an infant care training program, wherein the infant simulator

includes (A) a demand system comprising (i) a means for generating a perceptible demand signal (e.g., a crying sound), (ii) a means for inhibiting the demand signal in response to receipt of a satisfaction signal so long as the satisfaction signal is continuously received by the demand signal inhibiting means (e.g., holding a key within a keyhole against a biasing means), and (iii) a demand duration timer in communication with the demand signal generating means for terminating generation of the demand signal at the end of a demand period, and (B) a feedback system including (i) a means for generating a perceptible contented signal (e.g., a cooing sound), and (ii) a means for initiating generation of the contented signal at the end of the demand period provided the satisfaction signal is being received by the demand system at the end of the demand period (e.g., the cooing sound is generated only when the key is detected within the keyhole when the timer signals the end of the demand period). The contented signal thereby functions to indicate to a care provider that the demand period has ended, the demand signal has been terminated, and the satisfaction signal need no longer be continuously provided to the simulator (e.g., the care provider can remove the key from the keyhole).

*LEGAL REQUIREMENTS FOR ESTABLISHING  
PRIMA FACIE CASE OF OBVIOUSNESS*

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, NOT in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). *See*, M.P.E.P. § 2143.

*CITED REFERENCES LACK MOTIVATION  
TO MODIFY THE PRIOR ART DEVICES  
TO ACHIEVE THE PRESENT CLAIMED INVENTION*

The discussion provided in ¶3.1 above in connection with patentability of the Contented Signal Embodiment of the Present Claimed Invention in light of the NASCO Manual is equally applicable to this rejection as neither Corris et al. nor Schertz et al. disclose a contented signal feature.

**5.2**     INFANT SIMULATOR WITH  
IDENTIFICATION SYSTEM  
(CLAIMS 50, 52, 212, 215, 216, 255-256, 259 and 260)

*SUMMARY OF CITED REFERENCES*

**The NASCO Manual** discloses a parenting manikin programmed to periodically initiate care periods during which the manikin will cry until an appropriate care key - selected from a set of five different care keys- is inserted into the manikin. The NASCO Manual further discloses that the manikin will coo or burp when the correct care key is inserted, and then coo again several minutes later to indicate the end of the care period and the need to reinsert the same care key to avoid further crying.

**Corris et al.** (United States Patent No. 4,231,184) discloses a remote control doll capable of being remotely activated to cry and raise its arms. The crying sound can be interrupted by inserting a pacifier or bottle into the mouth of the doll.

**Schertz et al** (United States Patent No. 5,509,810) discloses an interactive neonatal resuscitation training simulator including a robotic infant capable of simulating the actions of a newborn requiring resuscitation (*e.g.*, low heart rate) and responding to the efforts of an attending physician to resuscitate the infant (*e.g.*, change color in response to receipt of appropriate medical care).

### *SUMMARY OF CLAIMED INVENTION*

The embodiment of **The Present Claimed Invention** as set forth in Claims 50, 52, 212, 215, 216, 254, 256, 259 and 260 (hereinafter "FIRST IDENTIFICATION SYSTEM EMBODIMENT"), is directed to an infant care simulation system for use in an infant care training program, wherein the infant simulator includes (A) a demand system comprising (i) a means for generating a perceptible demand signal (*e.g.*, a crying sound), and (ii) a means for arresting the demand signal in response to receipt of a satisfaction signal (*e.g.*, inserting a key within a keyhole), and (B) a care-provider identification system comprising (i) a means for receiving an identification signal (*e.g.*, keyhole effective for receiving an identification key attached to the wrist of an assigned care provider by a tamper indicating wristband), and (ii) a means effective for preventing arresting of the demand signal, even though the satisfaction signal has been received by the satisfaction signal arresting means, until the identification signal is received by the identification-signal receiving means.

The embodiment of **The Present Claimed Invention** as set forth in Claims 255, 256, 259 and 260 (hereinafter "SECOND IDENTIFICATION SYSTEM EMBODIMENT"), is directed to an infant care simulation system for use in an infant care training program, wherein the infant simulator includes (A) a demand system comprising (i) a means for generating a perceptible demand signal (*e.g.*, a crying sound), (ii) a means for receiving a satisfaction signal (*e.g.*, a keyhole for accepting insertion of a key), and (iii) a means for measuring and recording response time measured from initial generation of the perceptible demand signal to receipt of the satisfaction signal, and (B) a care-provider identification system comprising (i) a means for receiving an identification signal (*e.g.*, keyhole effective for receiving an identification key attached to the wrist of an assigned care provider by a tamper indicating wristband), and (ii) a means effective for causing continued measuring of the response time, even though the satisfaction signal has been received by the satisfaction signal arresting means, until the identification signal is received by the identification-signal receiving means.

*LEGAL REQUIREMENTS FOR ESTABLISHING  
PRIMA FACIE CASE OF OBVIOUSNESS*

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, NOT in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). *See*, M.P.E.P. § 2143.

*CITED REFERENCES LACK MOTIVATION  
TO MODIFY THE PRIOR ART DEVICES  
TO ACHIEVE THE PRESENT CLAIMED INVENTION*

The discussion provided in ¶3.2 above in connection with patentability of the First Identification System Embodiment of the Present Claimed Invention in light of the NASCO Manual is equally applicable to this rejection - as applied to both the First and Second Embodiments of the Identification System - as neither Corris et al. nor Schertz et al. disclose an identification system.

**5.3**     INFANT SIMULATOR WITH  
DIAPER-CHANGE SYSTEM  
(CLAIMS 48-50, 52-55, 58-60, and 62-69)

*SUMMARY OF CITED REFERENCES*

**The NASCO Manual** discloses a parenting manikin programmed to periodically initiate care periods during which the manikin will cry until an appropriate care key - selected from a set of five different care keys - is inserted into the manikin. The manikin is accompanied by a

“response sheet” upon which the care provider is instructed to mark the time of day they inserted one of the care keys.

**Corris et al.** (United States Patent No. 4,231,184) discloses a remote control doll capable of being remotely activated to cry and raise its arms. The crying sound can be interrupted by inserting a pacifier or bottle into the mouth of the doll.

**Schertz et al** (United States Patent No. 5,509,810) discloses an interactive neonatal resuscitation training simulator including a robotic infant capable of simulating the actions of a newborn requiring resuscitation (*e.g.*, low heart rate) and responding to the efforts of an attending physician to resuscitate the infant (*e.g.*, change color in response to receipt of appropriate medical care).

#### *SUMMARY OF CLAIMED INVENTION*

The embodiment of **The Present Claimed Invention** as set forth in claims 47, 49-50, 52-55, 58-60, and 62-69 (hereinafter “FIRST DIAPER-CHANGE EMBODIMENT”), is directed to an infant care simulation system for use in an infant care training program, wherein the infant simulator includes (A) a diaper-change system including at least (i) a means for generating a perceptible soiled-diaper signal (*e.g.*, a crying sound), and (ii) a means for arresting the soiled-diaper signal in response to receipt of a diaper-changed signal (*e.g.*, a magnetic actuated switch), and (B) a diaper having a means effective for transmitting the diaper-changed signal to the soiled-diaper signal arresting means when fitted on the doll (*e.g.*, a diaper having a magnet attached so as to be properly positioned and oriented to shut off the magnetic actuated switch when the diaper is fitted onto the doll).

The embodiment of **The Present Claimed Invention** as set forth in claims 48-49, 52-55, 58-60, and 62-69 (hereinafter “SECOND DIAPER-CHANGE EMBODIMENT”), is directed to an infant care simulation system for use in an infant care training program, wherein the infant simulator includes (A) a diaper-change system including at least (i) a means for generating a perceptible



soiled-diaper signal (e.g., a crying sound), and (ii) a means for receiving a diaper-changed signal (e.g., a magnetic actuated switch), and (iii) a means for measuring and recording response time measured from initial generation of the perceptible soiled-diaper signal to receipt of the diaper-changed signal, and (B) a diaper having a means effective for transmitting the diaper-changed signal to the diaper-changed signal receiving means when fitted on the doll (e.g., a diaper having a magnet attached so as to be properly positioned and oriented to shut off the magnetic actuated switch when the diaper is fitted onto the doll).

*LEGAL REQUIREMENTS FOR ESTABLISHING  
PRIMA FACIE CASE OF OBVIOUSNESS*

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, NOT in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). *See*, M.P.E.P. § 2143.

*CITED REFERENCES LACK MOTIVATION  
TO MODIFY THE PRIOR ART DEVICES  
TO ACHIEVE THE PRESENT CLAIMED INVENTION*

The discussion provided in ¶4.0 above in connection with patentability of the First Diaper-Change Embodiment of the Present Claimed Invention in light of the NASCO Manual in view of Corris et al. is equally applicable to this rejection - as applied to both the First and Second Embodiments of the Diaper Change System - as Schertz et al. does not disclose any aspect of a diaper change system.

**5.4** INFANT SIMULATOR WITH  
MEANS FOR MEASURING AND RECORDING RESPONSE TIME  
(CLAIMS 48-50, 52-55, 58-60, 62-69, 209-212, 215-217, 219-227, 255-256 AND 259-260)

It is noted for purposes of facilitating any further discussion regarding patentability of the Present Claimed Invention in light of the Schertz et al. reference, that Applicant was unable to locate any disclosure in the Schertz et al. reference as to a means for measuring and recording a physician's response time (e.g., measuring and recording time between signaling of lower heart rate and physician's injection of medication). In the event that the Examiner continues to rely upon Schertz et al. in a rejection of the Present Claimed Invention, Applicant respectfully requests that the Examiner identify with some degree of specificity that portion of Schertz et al. disclosing "... a means for timing and recording the duration of a demand problem episode." as argued by the Examiner in the Office Action.

**6.0** *The Examiner has rejected claim 61 as obvious over the NASCO Manual in view of Corris et al. and Schertz et al. and further in view of Lyons et al.*

*SUMMARY OF CITED REFERENCES*

**The NASCO Manual** discloses a parenting manikin programmed to periodically initiate care periods during which the manikin will cry until an appropriate care key - selected from a set of five different care keys- is inserted into the manikin. The manikin is accompanied by a "response sheet" upon which the care provider is instructed to mark the time of day they inserted one of the care keys.

**Corris et al.** (United States Patent No. 4,231,184) discloses a remote control doll capable of being remotely activated to cry and raise its arms. The crying sound can be interrupted by inserting a pacifier or bottle into the mouth of the doll.

**Schertz et al** (United States Patent No. 5,509,810) discloses an interactive neonatal resuscitation training simulator including a robotic infant capable of simulating the actions of a

newborn requiring resuscitation (*e.g.*, low heart rate) and responding to the efforts of an attending physician to resuscitate the infant (*e.g.*, change color in response to receipt of appropriate medical care).

**Lyons et al.** (United States Patent No. 4,160,338) discloses a doll capable of receiving water from a bottle through an oral orifice in the doll, and emitting the received water through the oral orifice to simulate “spitting-up” and/or through a posterior orifice to simulate wetting.

#### *SUMMARY OF CLAIMED INVENTION*

The embodiment of **The Present Claimed Invention** as set forth in Claim 61, (hereinafter “WET ASPECT OF SECOND DIAPER-CHANGE EMBODIMENT”), is directed to an infant care simulation system for use in an infant care training program, wherein the infant simulator includes (A) a diaper-change system including at least (i) a means for generating a perceptible soiled-diaper signal (*i.e.*, a wet diaper), (ii) a means for receiving a diaper-changed signal (*e.g.*, a magnetic actuated switch), and (iii) a means for measuring and recording response time measured from initial generation of the perceptible soiled-diaper signal to receipt of the diaper-changed signal, and (B) a diaper having a means effective for transmitting the diaper-changed signal to the soiled-diaper signal arresting means when fitted on the doll (*e.g.*, a magnet sewn into the diaper).

#### *LEGAL REQUIREMENTS FOR ESTABLISHING PRIMA FACIE CASE OF OBVIOUSNESS*

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, NOT in applicant’s disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). *See*, M.P.E.P. § 2143.

*CITED REFERENCES DO NOT TEACH OR SUGGEST  
ALL THE CLAIM LIMITATIONS OF  
THE PRESENT CLAIMED INVENTION*

None of the cited references disclose an infant simulator wherein a care provider must notice that the simulator has, on a schedule established by the simulator, wet his/her diaper, and then physically change the diaper in order to end timing of a response period measured from wetting of the diaper to changing of the diaper. The NASCO Manual describes the use of care keys inserted into a slot in the back of the manikin to stop crying, with the care provider manually recording the time of day they inserted the care key onto a "response sheet". Corris et al. describes the use of a pacifier or bottle inserted into the mouth of the doll to stop crying initiated by a remote control device. Schertz et al discloses subjecting a robotic infant to various resuscitation actions (*e.g.*, intubation, injection, etc.) directed to resuscitating an infant. Lyons et al. discloses a mechanism for permitting fluids introduced through the mouth of a doll to be discharged through a posterior opening in the doll, once the care-provider has introduced a sufficient amount of fluid into the doll, so as to simulate wetting. None of the cited references discloses a means for measuring and recording the responsiveness of a care provider (*e.g.*, how long was the infant simulator left in a wet diaper) nor do they require a care provider to actually diaper a doll/manikin in order to end the timing of such a response period.

As noted previously in this Amendment and Response, Applicant was unable to locate any disclosure in Schertz et al. of a means for measuring and recording the physician's response time . In the event that the Examiner maintains this rejection, Applicant respectfully requests that the Examiner identify with some degree of specificity that portion of Schertz et al. disclosing "... *a means for timing and recording the duration of a demand problem episode.*" as stated by the Examiner in the Office Action.

*CITED REFERENCES LACK MOTIVATION  
TO MODIFY THE PRIOR ART DEVICES  
TO ACHIEVE THE PRESENT CLAIMED INVENTION*

In order to determine the propriety of an obviousness rejection, it is necessary to ascertain whether or not the reference motivates one of ordinary skill in the relevant art, having the reference before him, to make the proposed substitution, combination, or other modification. In re Linter, 458 F.2d 1013, 173 USPQ 560, 562 (CCPA 1972). Obviousness can only be established where there is some teaching, suggestion or motivation in the prior art or in the knowledge generally available to one of ordinary skill in the art, to combine the references and produce the claimed invention. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *See*, M.P.E.P. §2143.01.

The discussion provided in ¶ 5.3 above (referencing ¶ 4.0) in connection with patentability of the Second Diaper-Change Embodiment of the Present Claimed Invention in light of the NASCO Manual in view of Corris et al. and Schertz et al., is equally applicable to this rejection as Lyons et al. does not disclose any aspect of a diaper change system. Lyons et al. merely discloses a mechanism for permitting fluids orally introduced into a doll to be discharged so as to simulate wetting. Lyons et al. does not teach or suggest incorporating such wetting action into an infant simulator having a means for measuring and recording the responsiveness of a care-provider by measuring and recording the time between wetting of the diaper and changing of the diaper. Lyons et al. simply discloses that such wetting action enhances the play value of the toy by permitting a care provider to cause the doll to wet a diaper as desired (*i.e.*, whenever the care provider feeds the doll a sufficient amount of fluid from a bottle) and allow the care provider to change, or not change, the wetted diaper as desired. *See*, column 5, lines 60-64.

7.0 *The Examiner has rejected claims 56, 57, 218, 236, 237 and 240-253 as obvious over the NASCO Manual in view of Corris et al. and Schertz et al. and further in view of DeFino et al.*

7.1 INFANT SIMULATOR WITH  
CONTENTED SIGNAL FEATURE  
(CLAIM 218)

*SUMMARY OF CITED REFERENCES*

**The NASCO Manual** discloses a parenting manikin programmed to periodically initiate care periods during which the manikin will cry until an appropriate care key - selected from a set of five different care keys- is inserted into the manikin. The NASCO Manual further discloses that the manikin will coo or burp when the correct care key is inserted, and then coo again several minutes later to indicate the end of the care period and the need to reinsert the same care key to avoid further crying.

**Corris et al.** (United States Patent No. 4,231,184) discloses a remote control doll capable of being remotely activated to cry and raise its arms. The crying sound can be interrupted by inserting a pacifier or bottle into the mouth of the doll.

**Schertz et al** (United States Patent No. 5,509,810) discloses an interactive neonatal resuscitation training simulator including a robotic infant capable of simulating the actions of a newborn requiring resuscitation (*e.g.*, low heart rate) and responding to the efforts of an attending physician to resuscitate the infant (*e.g.*, change color in response to receipt of appropriate medical care).

**DeFino et al.** (United States Patent No. 4,160,338) discloses an automobile intruder alarm system for producing a tone upon entry into the automobile through a door for purposes of audibly signaling that the alarm was activated when the automobile was entered and will sound unless deactivated within a defined time period. DeFino et al. further discloses that the alarm

system can increase the frequency or volume of the tone as the amount of time remaining to deactivate the alarm decreases.

#### *SUMMARY OF CLAIMED INVENTION*

The embodiment of **The Present Claimed Invention** as set forth in Claim 218 (hereinafter "CONTENTED SIGNAL EMBODIMENT WITH ESCALATING DEMAND SIGNAL"), is directed to an infant care simulation system for use in an infant care training program, wherein the infant simulator includes (A) a demand system comprising (i) a means for generating a perceptible demand signal (*e.g.*, a crying sound), (ii) a means for inhibiting the demand signal in response to receipt of a satisfaction signal so long as the satisfaction signal is continuously received by the demand signal inhibiting means (*e.g.*, holding a key within a keyhole against a biasing means), and (iii) a demand duration timer in communication with the demand signal generating means for terminating generation of the demand signal at the end of a demand period, (B) a means for escalating the intensity of the demand signal as the duration between generation of the demand signal and receipt of the satisfaction signal increases, and (C) a feedback system including (i) a means for generating a perceptible contented signal (*e.g.*, a cooing sound), and (ii) a means for initiating generation of the contented signal at the end of the demand period provided the satisfaction signal is being received by the demand system at the end of the demand period (*e.g.*, the cooing sound is generated only when the key is detected within the keyhole when the timer signals the end of the demand period). The contented signal accordingly functions to indicate to a care provider that the demand period has ended, the demand signal has been terminated, and the satisfaction signal need no longer be continuously provided to the simulator (*i.e.*, the care provider can stop providing the satisfaction signal, such as rocking of the infant simulator).

#### DEFINO ET AL. IS NONANALOGOUS ART

DeFino et al. is directed to the field of intruder alarms. The Present Claimed Invention is directed to infant simulators. The construction, use and function of these two types of products are completely different (*e.g.*, intruder alarms are designed to detect the presence of an intruder and emit a warning signal for purposes of preventing unauthorized entry or use, while infant simulators

are designed to require a care-provider to interact with the infant simulator for purposes of simulating the care requirements of an infant and reporting the level of care provided by the care-provider to a program administrator). Due to such differences in the construction and function of such devices, those skilled in the art of designing infant simulators do not look to intruder alarm systems for guidance in the design of an infant simulator. *See*, M.P.E.P. §2141.01(a). Hence, it is inappropriate to combine DeFino et al. with the other cited references in an effort to achieve the Present Claimed Invention.

*CITED REFERENCES LACK MOTIVATION  
TO MODIFY THE PRIOR ART DEVICES  
TO ACHIEVE THE PRESENT CLAIMED INVENTION*

The discussion provided in ¶5.1 (referencing ¶3.1) above in connection with patentability of the Contented Signal Embodiment of the Present Claimed Invention in light of the NASCO Manual in view of Corris et al. and Schertz et al. is equally applicable to this rejection as (i) DeFino et al. is directed to a nonanalogous art and cannot be properly combined with the other references, and (ii) DeFino et al. does not disclose any aspect of a contented signal feature.

**7.2**     INFANT SIMULATOR WITH  
IDENTIFICATION SYSTEM FEATURE  
(CLAIMS 237, 240 and 241)

*SUMMARY OF CITED REFERENCES*

**The NASCO Manual** discloses a parenting manikin programmed to periodically initiate care periods during which the manikin will cry until an appropriate care key - selected from a set of five different care keys- is inserted into the manikin. The NASCO Manual further discloses that the manikin will coo or burp when the correct care key is inserted, and then coo again several minutes later to indicate the end of the care period and the need to reinsert the same care key to avoid further crying.



**Corris et al.** (United States Patent No. 4,231,184) discloses a remote control doll capable of being remotely activated to cry and raise its arms. The crying sound can be interrupted by inserting a pacifier or bottle into the mouth of the doll.

**Schertz et al** (United States Patent No. 5,509,810) discloses an interactive neonatal resuscitation training simulator including a robotic infant capable of simulating the actions of a newborn requiring resuscitation (*e.g.*, low heart rate) and responding to the efforts of an attending physician to resuscitate the infant (*e.g.*, change color in response to receipt of appropriate medical care).

**DeFino et al.** (United States Patent No. 4,160,338) discloses an automobile intruder alarm system for producing a tone upon entry into the automobile through a door for purposes of audibly signaling that the alarm was activated when the automobile was entered and will sound unless deactivated within a defined time period. DeFino et al. further discloses that the alarm system can increase the frequency or volume of the tone as the amount of time remaining to deactivate the alarm decreases.

#### *SUMMARY OF CLAIMED INVENTION*

The embodiment of **The Present Claimed Invention** as set forth in Claims 237, 240 and 241 (hereinafter "FIRST IDENTIFICATION SYSTEM EMBODIMENT WITH ESCALATING DEMAND SIGNAL"), is directed to an infant care simulation system for use in an infant care training program, wherein the infant simulator includes (A) a demand system comprising (i) a means for generating a perceptible demand signal, and (ii) a means for arresting the demand signal in response to receipt of a satisfaction signal, (B) a means for escalating the intensity of the demand signal as the response time increases, and (C) a care-provider identification system comprising (i) a means for receiving an identification signal, and (ii) a means effective for preventing arresting of the demand signal, even though the satisfaction signal has been received by the satisfaction signal arresting means, until the identification signal is received by the identification-signal receiving means.

DEFINO ET AL. IS FROM NONANALOGOUS ART

DeFino et al. is directed to the field of intruder alarms. The Present Claimed Invention is directed to infant simulators. The construction, use and function of these two types of products are completely different (*e.g.*, intruder alarms are designed to detect the presence of an intruder and emit a warning signal for purposes of preventing unauthorized entry or use, while infant simulators are designed to require a care-provider to interact with the infant simulator for purposes of simulating the care requirements of an infant and reporting the level of care provided by the care-provider to a program administrator). Due to such differences in the construction and function of such devices, those skilled in the art of designing infant simulators do not look to intruder alarm systems for guidance in the design of an infant simulator. *See*, M.P.E.P. §2141.01(a). Hence, it is inappropriate to combine DeFino et al. with the other cited references in an effort to achieve the Present Claimed Invention.

*CITED REFERENCES LACK MOTIVATION  
TO MODIFY THE PRIOR ART DEVICES  
TO ACHIEVE THE PRESENT CLAIMED INVENTION*

The discussion provided in ¶5.2 above (referencing ¶3.2) in connection with patentability of the First Identification System Embodiment of the Present Claimed Invention in light of the NASCO Manual in view of Corris et al. and Schertz et al is equally applicable to this rejection as (i) DeFino et al. is directed to a nonanalogous art and cannot be properly combined with the other references, and (ii) DeFino et al. does not disclose any aspect of an identification system.

7.3 INFANT SIMULATOR WITH  
DIAPER-CHANGE SYSTEM FEATURE  
(CLAIMS 56 AND 57)

*SUMMARY OF CITED REFERENCES*

**The NASCO Manual** discloses a parenting manikin programmed to periodically initiate care periods during which the manikin will cry until an appropriate care key - selected from a set of five different care keys- is inserted into the manikin.

**Corris et al.** (United States Patent No. 4,231,184) discloses a remote control doll capable of being remotely activated to cry and raise its arms. The crying sound can be interrupted by inserting a pacifier or bottle into the mouth of the doll.

**Schertz et al** (United States Patent No. 5,509,810) discloses an interactive neonatal resuscitation training simulator including a robotic infant capable of simulating the actions of a newborn requiring resuscitation (*e.g.*, low heart rate) and responding to the efforts of an attending physician to resuscitate the infant (*e.g.*, change color in response to receipt of appropriate medical care).

**DeFino et al.** (United States Patent No. 4,160,338) discloses an automobile intruder alarm system for producing a tone upon entry into the automobile through a door for purposes of audibly signaling that the alarm was activated when the automobile was entered and will sound unless deactivated within a defined time period. DeFino et al. further discloses that the alarm system can increase the frequency or volume of the tone as the amount of time remaining to deactivate the alarm decreases.

*SUMMARY OF CLAIMED INVENTION*

The embodiment of **The Present Claimed Invention** as set forth in Claims 56 and 57, (hereinafter "DIAPER-CHANGE EMBODIMENT WITH ESCALATING SOILED-DIAPER SIGNAL"), encompasses both the First and Second Diaper-Change Embodiments, with the embodiments

further including a means for escalating the intensity of the soiled-diaper signal as response time increases.

As described previously, the FIRST DIAPER-CHANGE EMBODIMENT is directed to an infant care simulation system for use in an infant care training program, wherein the infant simulator includes (A) a diaper-change system including at least (i) a means for generating a perceptible soiled-diaper signal (*e.g.*, a crying sound), and (ii) a means for arresting the soiled-diaper signal in response to receipt of a diaper-changed signal (*e.g.*, a magnetic actuated switch), and (B) a diaper having a means effective for transmitting the diaper-changed signal to the soiled-diaper signal arresting means when fitted on the doll (*e.g.*, a diaper having a magnet attached so as to be properly positioned and oriented to shut off the magnetic actuated switch when the diaper is fitted onto the doll).

Also as described previously, the SECOND DIAPER-CHANGE EMBODIMENT is directed to an infant care simulation system for use in an infant care training program, wherein the infant simulator includes (A) a diaper-change system including at least (i) a means for generating a perceptible soiled-diaper signal (*e.g.*, a crying sound), (ii) a means for receiving a diaper-changed signal (*e.g.*, a magnetic actuated switch), and (iii) a means for measuring and recording response time measured from initial generation of the perceptible soiled-diaper signal to receipt of the diaper-changed signal, and (B) a diaper having a means effective for transmitting the diaper-changed signal to the diaper-changed signal receiving means when fitted on the doll (*e.g.*, a diaper having a magnet attached so as to be properly positioned and oriented to shut off the magnetic actuated switch when the diaper is fitted onto the doll).

DEFINO ET AL. IS FROM NONANALOGOUS ART

DeFino et al. is directed to the field of intruder alarms. The Present Claimed Invention is directed to infant simulators. The construction, use and function of these two types of products are completely different (*e.g.*, intruder alarms are designed to detect the presence of an intruder and emit a warning signal for purposes of preventing unauthorized entry or use, while infant simulators are designed to require a care-provider to interact with the infant simulator for purposes of

simulating the care requirements of an infant and reporting the level of care provided by the care-provider to a program administrator). Due to such differences in the construction and function of such devices, those skilled in the art of designing infant simulators do not look to intruder alarm systems for guidance in the design of an infant simulator. *See*, M.P.E.P. §2141.01(a). Hence, it is inappropriate to combine DeFino et al. with the other cited references in an effort to achieve the Present Claimed Invention.

*CITED REFERENCES LACK MOTIVATION  
TO MODIFY THE PRIOR ART DEVICES  
TO ACHIEVE THE PRESENT CLAIMED INVENTION*

The discussion provided in ¶5.3 above (referencing ¶4.0) in connection with patentability of the First and Second Diaper-Change System Embodiments of the Present Claimed Invention in light of the NASCO Manual in view of Corris et al. and Schertz et al., is equally applicable to this rejection as (i) DeFino et al. is directed to a nonanalogous art and cannot be properly combined with the other references, and (ii) DeFino et al. does not disclose any aspect of a diaper-change system.

**7.4**    INFANT SIMULATOR WITH  
ESCALATING DEMAND FEATURE  
(CLAIMS 56, 57, 218, 236, 237 and 240-253)

*SUMMARY OF CITED REFERENCES*

**The NASCO Manual** discloses a parenting manikin programmed to periodically initiate care periods during which the manikin will cry until an appropriate care key - selected from a set of five different care keys- is inserted into the manikin. The NASCO Manual further discloses that the manikin will coo or burp when the correct care key is inserted, and then coo again several minutes later to indicate the end of the care period and the need to reinsert the same care key to avoid further crying.

**Corris et al.** (United States Patent No. 4,231,184) discloses a remote control doll capable of being remotely activated to cry and raise its arms. The crying sound can be interrupted by inserting a pacifier or bottle into the mouth of the doll.

**Schertz et al** (United States Patent No. 5,509,810) discloses an interactive neonatal resuscitation training simulator including a robotic infant capable of simulating the actions of a newborn requiring resuscitation (*e.g.*, low heart rate) and responding to the efforts of an attending physician to resuscitate the infant (*e.g.*, change color in response to receipt of appropriate medical care).

**DeFino et al.** (United States Patent No. 4,160,338) discloses an automobile intruder alarm system for producing a tone upon entry into the automobile through a door for purposes of audibly signaling that the alarm was activated when the automobile was entered and will sound unless deactivated within a defined time period. DeFino et al. further discloses that the alarm system can increase the frequency or volume of the tone as the amount of time remaining to deactivate the alarm decreases.

#### *SUMMARY OF CLAIMED INVENTION*

The embodiment of **The Present Claimed Invention** as set forth in Claims 56, 57, 218, 236, 237 and 240-253 (hereinafter INFANT SIMULATOR WITH ESCALATING DEMAND SIGNAL) is directed to an infant care simulation system for use in an infant care training program, wherein the infant simulator includes (A) a demand system comprising (i) a means for generating a perceptible demand signal, and (ii) a means for arresting the demand signal in response to receipt of a satisfaction signal, and (B) a means for escalating the intensity of the demand signal as the duration between generation of the demand signal and receipt of the satisfaction signal increases.

LEGAL REQUIREMENTS FOR ESTABLISHING  
PRIMA FACIE CASE OF OBVIOUSNESS

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, NOT in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). *See*, M.P.E.P. § 2143.

NASCO MANUAL, CORRIS ET AL. AND SCHERTZ ET AL  
DO NOT DISCLOSE ESCALATING DEMAND FEATURE

The Examiner acknowledges that the NASCO Manual, Corris et al. and Schertz et al. do not teach or suggest escalation of a demand signal (*e.g.*, increasing the intensity of a crying sound).

DEFINO ET AL. IS FROM NONANALOGOUS ART

DeFino et al. is directed to the field of intruder alarms. The Present Claimed Invention is directed to infant simulators. The construction, use and function of these two types of products are completely different (*e.g.*, intruder alarms are designed to detect the presence of an intruder and emit a warning signal for purposes of preventing unauthorized entry or use, while infant simulators are designed to require a care-provider to interact with the infant simulator for purposes of simulating the care requirements of an infant and reporting the level of care provided by the care-provider to a program administrator). Due to such differences in the construction and function of such devices, those skilled in the art of designing infant simulators do not look to intruder alarm systems for guidance in the design of an infant simulator. *See*, M.P.E.P. §2141.01(a). Hence, it is inappropriate to combine DeFino et al. with the other cited references in an effort to achieve the Present Claimed Invention.

*CITED REFERENCES LACK MOTIVATION  
TO MODIFY THE PRIOR ART DEVICES  
TO ACHIEVE THE PRESENT CLAIMED INVENTION*

In order to determine the propriety of an obviousness rejection, it is necessary to ascertain whether or not the reference motivates one of ordinary skill in the relevant art, having the reference before him, to make the proposed substitution, combination, or other modification. In re Linter, 458 F.2d 1013, 173 USPQ 560, 562 (CCPA 1972). Obviousness can only be established where there is some teaching, suggestion or motivation in the prior art or in the knowledge generally available to one of ordinary skill in the art, to combine the references and produce the claimed invention. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *See*, M.P.E.P. §2143.01.

As mentioned above, the NASCO Manual, Corris et al. and Schertz et al. do not teach or suggest escalation of a demand signal, with the NASCO Manual the only reference actually directed to the field of infant simulators. While DeFino et al. teaches escalation of a warning tone, DeFino et al. is directed to use of such a feature in connection with the deactivation of an automobile intruder alarm system. There is simply nothing in any of the cited references motivating one skilled in the art to select the tone escalation feature from DeFino et al. and incorporate that feature into a parenting manikin.

Furthermore, it is noted that - absent use of Applicant's disclosure as a blueprint - even a combination of the cited references would not result in the Present Claimed Invention. Indeed, absent use of Applicant's disclosure as a blueprint, a combination of the cited references produces the parenting manikin disclosed in the NASCO Manual modified to produce a tone prior to initiation of crying for purposes of permitting a care-provider to "deactivate" the crying sound before the care period is commenced, with the volume and/or frequency of the tone increasing as the care period is approached.



## CONCLUSION

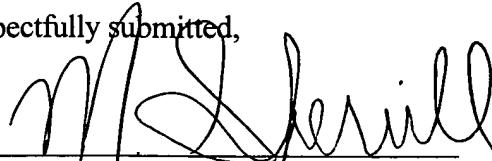
Applicant respectfully submits that all pending claims are in condition for allowance.

Date

22 Oct 98

Respectfully submitted,

By





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